

K 952478/52

**510(k) Summary of Safety and Efficacy Upon Which  
Substantial Equivalence is Based**

**Cardiac T™ Troponin T Rapid Assay**

The Boehringer Mannheim Cardiac T Troponin T Rapid Assay is substantially equivalent to the currently marketed Boehringer Mannheim ELISA Troponin T assay. Both tests are intended for the detection of Troponin T. The procedure for both assays utilize the same cardiac specific antibodies to detect troponin-T in specimens.

External evaluations in 8 institutions involving 483 cardiac patients were tested. Comparing the Rapid Assay to the ELISA method yielded the following:

CARDIAC T RAPID Assay Result	ELISA Troponin T Result	
	≥ 0.2 ng/mL	< 0.2 ng/mL
Positive	147	9
Negative	14	313